The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN SEFTON

Appeal No. 2002-1369
Application 09/367,712

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and POTEATE, Administrative Patent Judges.

POTEATE, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's refusal to allow claims 1-3, 5-8 and 10-13, which are all of the claims pending in the application. Claim 1 is representative of the subject matter on appeal and is reproduced below:

1. A method for treating proliferative skin diseases comprising the administration of an effective amount of tazarotene and an effective amount of a mid-or high-potency corticosteroid.

The references relied upon by the examiner are:

Sequeira et al. (Sequeira)	4,775,529	Oct. 4, 1988
Yamamoto	5,236,906	Aug. 17, 1993
Nagpal et al. (Nagpal)	5,650,279	Jul. 22, 1997
Smith	5,874,074	Feb. 23, 1999

GROUNDS OF REJECTION

1. Claims 1-3, 5-8 and 10-13 stand rejected under 35 U.S.C. § 103 as unpatentable over Yamamoto and Nagpal.

2. Claim 2 stands rejected under 35 U.S.C. § 103 as unpatentable over Smith or Sequeira in combination with Nagpal.

We affirm as to the first ground of rejection, but denominate our rejection as a new ground of rejection under 37 CFR § 1.196(b) for the reasons set forth below. Having concluded that the claims are unpatentable over Yamamoto and Nagpal, we do not reach the second ground of rejection.

DISCUSSION

The invention is directed to a method of treating proliferative skin diseases, e.g., psoriasis, in humans comprising administering an effective amount of tazarotene and an effective amount of a mid- or high-potency corticosteroid. In a preferred embodiment, the corticosteroid is selected from the group consisting of alclometasone dipropionate, momentasone furoate, and betamethasone valerate. Claim 2. According to

appellant, the combination of tazarotene and a mid- or high-potency corticosteroid provides a synergistic effect. Appeal Brief, Paper No. 11, received January 12, 2001, page 2.

The examiner found that Yamamoto teaches that it is known in the art to use adrenocortical hormones which are among those utilized by appellant for treatment of skin diseases including psoriasis. See Examiner's Answer, Paper No. 12, mailed March 8, 2001, page 3. The examiner further found that Nagpal discloses that it is known to use tazarotene for treatment of psoriosis. Id. The examiner concludes that it would have been prima facie obvious to one of ordinary skill in the art to have used the combination of mid- or high-potency corticosteroid and tazarotene for the treatment of proliferative skin diseases as claimed in view of the combined teachings of Yamamoto and Nagpal. See id., page 4. In so concluding, the examiner cites In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980) for the proposition that it is obvious to use the combination of two compounds/compositions taught by the prior art to be useful for the same purpose to form a third composition. Id.

Appellant is in agreement with the examiner's findings with respect to the teachings of the individual references. See Appeal Brief, page 4. However, appellant argues that the

examiner has not supplied the requisite motivation to combine the cited references to achieve the claimed invention. See id., page 5.

We disagree with appellant and conclude that the examiner has provided proper motivation for combining the references in accordance with the decision in Kerkhoven. Accordingly, we find that the examiner has established a prima facie case of obviousness.

A prima facie case of obviousness may be rebutted if the appellant shows that the art, in any material respect, teaches away from the claimed invention. In re Malagari, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974). Appellant argues that "Yamamoto '906 teaches away from the use of corticosteroids at the usual clinical doses in combination with active ingredients." Appeal Brief, page 5. In this regard, appellant notes that Yamamoto dilutes the "effective and usual concentration" of fluocinonide, i.e., .05%, to .015% or .005%. We do not find this argument persuasive since the Specification indicates that an effective amount of corticosteroid is in the preferred range of from about .005% to about .1% by weight of the composition. See Specification, page 5, lines 15-18.

A prima facie case of obviousness may be rebutted by

evidence showing that the claimed composition has "unexpected" properties which are not possessed by the prior art. In re Papesch, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963). Appellant argues that the Specification provides evidence that mid- or high-potency corticosteroids in combination with tazarotene exhibit a synergistic effect, i.e., that the combination provides a more effective treatment of psoriasis than tazarotene alone, or in combination with a low-potency corticosteroid. Appeal Brief, pages 5-6. We have reviewed the evidence presented in the Specification and conclude that it is not persuasive in overcoming the examiner's prima facie showing of obviousness.

Referring, first, to Example 1, the results of which are set forth in Figure 1, we note that the combination of tazarotene and a low-potency corticosteroid appear to provide better results than the combination of tazarotene and a mid-potency corticosteroid in reducing the severity of psoriasis in patients treated over a period of 12 weeks. The mean severity was approximately the same for patients treated with these compositions after a further 4 week post-treatment. Moreover, it is impossible to conclude from Table II that the incidence of adverse events was consistently lower in patients treated with

mid- or high-potency corticosteroid in combination with tazarotene as compared with patients treated with low-potency corticosteroid in combination with tazarotene, or tazarotene alone. In particular, we note that patients suffered greater burning when treated with a combination of tazarotene and high-potency corticosteroid and a higher incidence of pruritus when treated with a combination of mid-potency corticosteroid and tazarotene.

Figure 2 shows treatment success in patients over a 12 week treatment period and four week post treatment period using the same four compositions. As with the results shown in Figure 1, it appears that the combination of low-potency corticosteroid and tazarotene provides better results than the combination of mid-potency corticosteroid and tazarotene.

We have also reviewed Example 2 of the Specification wherein appellant indicates that Example 1 was repeated using different corticosteriods in combination with tazarotene. See Specification, page 13. We do not find this Example persuasive in demonstrating unexpected results since the Example is unsupported by any data and is merely appellant's assertions that higher treatment success rates and decreased incidence of adverse events were provided when tazarotene was utilized in combination

with mid- or high-potency corticosteroids.

Accordingly, we conclude that appellant's evidence of unexpected results is insufficient to overcome the examiner's prima facie showing of obviousness. However, as the examiner failed to comment on appellant's evidence, we denominate our affirmance of the rejection as a new ground of rejection under 37 CFR § 1.196(b). See In re Wagner, 371 F.2d 877, 883, 152 USPQ 552, 558 (CCPA 1967) (proof of facts may be controverted by the Patent Office but cannot be ignored).

Having concluded that all of the claims are unpatentable under 35 U.S.C. § 103 in view of the combined teachings of Yamamoto and Nagpal[1], we do not reach the separate rejection of claim 2 under 35 U.S.C. § 103 as unpatentable over Smith or Sequeira in view of Nagpal.

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[1]Appellant argues that claims 1-3, 5 and 12 are separately patentable from claims 6-8, 10, 11 and 13. Appeal Brief, page 3. However, appellant appears to present the same arguments with respect to both groups of claims in that he argues that the data provided in Examples 1 and 2 support the patentability of both groups of claims. See Appeal Brief, pages 6 and 7.

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED; 37 CFR 1.196(b)

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